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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/587,212

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/587,212	Applicant(s) TAKIZAWA ET AL.	
	Examiner Bao-Thuy L. Nguyen	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-25 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/5/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment dated 13 March 2009 has been received. Claims 1-25 and 31 have been withdrawn.
2. Claims 26-30 are pending and are under consideration.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 26-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown, III et al., (US 4,916,056).

Brown discloses a flow-through assay device comprising lyophilized labeled reagents which may be disposed in a prefilter apparatus and a fibrous material having immobilized capture reagent. See column 8, lines 11-20.

With respect to claim 27, Brown discloses enzymes labels. See example 3.

With respect to claims 28 and 29, Brown teaches the detection of antigens or antibodies using the appropriate binding partners. See column 3, lines 45-50 and columns 5-6.

With respect to claim 30, Brown teaches the use of glass fiber paper as the fibrous material. See example 2.

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Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cole (WO 03/016902) in view of Cole et al (US 5,141,850).

Cole discloses a flow-through apparatus comprising a first member having a first, porous, reaction membrane to which is bound a capture analyte for binding to a reagent to be detected. A chamber above the first member having side walls and a base defined by a second membrane. In use, sample and labeled reagent is added to the chamber and allow to flow through to the reaction membrane. See page 4.

Cole differs from the instant invention in failing to teach that the labeled reagent is immobilized in a porous material.

Cole, '850, however, teaches a device where the labeled reagents may be provided separately from the porous membrane containing the capture reagents or provided together on the same dipstick. See column 2, line 63 through column 3, line 37. '850 teaches gold sol particles as labels. Column 6, lines 15-23. '850 teaches the detection of analytes such as antigens and antibodies using appropriate binding partners. Column 9. The solid phase materials taught by '850 comprise cellulose and other equivalent materials. See column 3, line 59 through column 4, line 59.

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Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device taught by Cole (WO 03/016902) by immobilizing the labeled reagent into the second membrane because '850 teaches that having labels reagents in solid or liquid phase is functionally equivalent.

A skilled artisan would have had a reasonable expectation of success in impregnating the labeled reagent in the second membrane because Cole '850 teaches that it is well known in the art to provide a simplified, inexpensive, efficient, fool-proof, pre-package, one step device that has a good shelf life characteristics.

Response to Arguments

7. Applicant's arguments filed 13 March 2009 have been fully considered but they are not persuasive.

Applicant argues that Brown does not teach that the prefilter 22d comprises labeled reagents containing ligands which specifically bind to an analyte and does not play a role for contacting and mixing the analyte and the labeled reagent.

This argument is not persuasive. Brown teaches that the prefilter is made of the same porous material as the instant claim. Brown also teaches that the prefilter 22 can perform such function as a reservoir to retain sample or slow the passage of sample or reagents to the reaction matrix, as a vehicle to retain reagents, e.g. lyophilized reagents, to be used in the assay. See column 8, lines 14-18. The lyophilized reagents are disclosed in example 2 as antibody coated microparticles. Brown teaches that the prefilter can be removed from the device but does not need to be. See column 8, lines 21-32. Clearly, if the prefilter is made of the same porous

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material as the instant claims and it is an integral part of the device, it should inherently possess the same characteristics, i.e. the ability to mix with the sample analyte while in the prefilter.

Although Brown does not specifically state that the antibody coated particles are the labeled reagents, a skilled artisan can clearly see that particulate labels are well known in the art.

Applicant argues that Cole '902 and Col '850 do not make obvious the instant claim because Cole '902 does not teach porous material impregnated with labeled reagents and Col '850 does not teach the same reaction dynamics as the instant claims.

This argument is not persuasive. In response to applicant's argument that the reaction dynamics of Cole '850 is not the same with that of the instant claim, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, Cole '920 teaches the invention substantially as claimed. Cole '920 differs from the instant claims in failing to teach that the labeled reagents are disposed in the porous membrane.

However, Cole '850 discloses that it is well known in the art to place the labeled reagent into the second membrane because having labels reagents in solid or liquid phase is functionally equivalent.

Conclusion

8. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Monday -- Thursday from 9:00 a.m. - 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Bao-Thuy L. Nguyen/

Primary Examiner, Art Unit 1641

June 24, 2009